

REMARKS

This application contains allowed claims 33, 34 and 49-52, 54, 55 and 57-60 and currently-rejected claim 61. Claims 33, 59, 60 and 61 are the only pending independent claims. Thus, claim 61 is the only rejected pending claim in the outstanding Office Action, which was surprising to Applicants, since the Advisory Action of February 27, 2009 indicated that claim 61 was allowed.

Claim 61, amended in its current form in the Amendment After Final Rejection (submitted with a Request for Continued Prosecution), filed January 22, 2009, and last presented in the Supplemental Amendment After Final Rejection, filed March 25, 2009, is as follows:

61. An isolated protein having at least 90% sequence identity to SEQ ID NO:23 or SEQ ID NO:35, wherein the isolated protein is not a wild-type NhhA polypeptide and wherein the isolated protein is immunogenic.

The sole ground of rejection relied upon by the Examiner is that claim 61 allegedly would have been obvious over WO99/31132 (Peak).

As a formal matter, the Office Action did not identify the basis under section 102 whereby Peak is considered a prior art reference citable in support of a section 103(a) obviousness rejection. Nevertheless, to facilitate substantively responding to the Office Action, we will proceed on the basis that the Examiner considers Peak to be citable prior art under section 102(a), based on the prosecution history to date.

The Examiner has argued that Peak allegedly teaches an ORF40-1 protein that has 98.1% identity to SEQ ID NO:23 and has 99.3% identity to SEQ ID NO:35. Applicants respectfully point out that this is not correct.

Firstly, Peak does not teach an ORF 40-1 protein at all. This protein designation is not present in Peak. There is no basis stated in the Office Action for the comparison made by the Examiner. Presumably, it is SEQ ID NO:5 of Peak (per page 3 of the Office Action), although it is not clear why the Examiner has selected this particular protein from the 10 NhhA wild type proteins described by Peak. At this stage, whatever the case, we will proceed on the basis of this assumption.

Secondly, whatever the protein is in Peak that the Examiner considers to be relevant to

this rejection, the Examiner seems to be comparing a sub-region of the full length sequence (*e.g.* SEQ ID NO:5) with the entire respective sequences of SEQ ID NO:23 and SEQ ID NO:35, in hindsight. This seems to be based on the Examiner's identification of disclosure in Peak about fragments comprising at least 6, 10 or 20 amino acids, inclusive of deletion mutants. However, Peak does not teach or suggest the particular sub-region of any of the protein sequences therein that the Examiner is comparing with SEQ ID NO:23 and SEQ ID NO:35.

Claim 61 requires that the 90% identity be with respect to SEQ ID NO:23 or SEQ ID NO:35. Claim 61 does not recite proteins having at least 90% identity with any wild-type NhhA polypeptide, fragment or deletion mutant. It is only when armed with the invention defined by claim 61 that the Examiner has selected the sub-region of Peak SEQ ID NO:5 to compare with SEQ ID NOS:23 and 35. One skilled in the art, at the time of the present invention, without the benefit of the present invention, would not have selected this sub-region of Peak SEQ ID NO:5 as meaningful, compared to the present invention.

Each of SEQ ID NOS: 23 and 35 lacks most of the hypervariable V1 region sequence, as well as the entire V2 and C2 region sequences. Furthermore, SEQ ID NO:35 lacks the processed N-terminal sequence of C1.

To perform the sequence comparison with SEQ ID NO:23 set forth in the Office Action, the Examiner has had to exclude the hypervariable V1 region sequence and the V2 and C2 sequences from SEQ ID NO:5 of Peak, even though these regions were not described by Peak, let alone suggested as suitable regions to delete from wild-type SEQ ID NO:5. In other words, the Examiner (or at least the sequence comparison algorithm used by the Examiner) has had to ignore (*i.e.* effectively delete) these regions to perform the sequence comparison and arrive at the 98.1% identity level recited by the Examiner.

Likewise, to perform the sequence comparison with SEQ ID NO:35 set forth in the Office Action, the Examiner has had to exclude the hypervariable V1 region sequence, the V2 region and C2 region sequences and the C1 region sequence from SEQ ID NO:5 of Peak, even though these regions were not described by Peak, let alone suggested as suitable regions to delete from wild-type SEQ ID NO:5. Despite this, the Examiner (or at least the sequence comparison algorithm used by the Examiner) has had to ignore (*i.e.* effectively delete) these regions to perform the sequence comparison and arrive at the 99.3% identity level recited by the Examiner.

Applicants respectfully submit that the Examiner's approach has been to impermissibly compare SEQ ID NOS:23 and 35 with SEQ ID NO:5 of Peak in hindsight, and then arbitrarily, based only on the present invention's disclosure, to identify sub-sequences in the Peak full length sequence having greater than 90% identity with SEQ ID NOS:23 and 35. These sub-regions were not taught or suggested by Peak, nor is there any knowledge held by a person of ordinary skill in the art that would lead such a person to identify the sub-sequences of SEQ ID NO:5 of Peak relied upon by the Examiner to allege that Peak discloses sequences at least 90% identical to SEQ ID NOS:23 and 35.

Since the basis of the comparison is erroneous and based only on the hindsight of the present application, reconsideration and withdrawal of the rejection of claim 61 are respectfully but strenuously requested.

Applicants respectfully submit that the present application is now in full condition for allowance and an early Notice of Allowance of all pending claims is respectfully solicited.

Respectfully submitted,

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(Date)

By: _____


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